

**REMARKS**

Applicants have carefully reviewed the Office Action dated July 5, 2006 regarding the above-referenced patent application. Claims 1-32 are pending, claims 11-16 and 27-32 have been withdrawn from consideration, claims 1-3, 5, 8-10 and 18-26 have been rejected, and claims 4, 6, 7, and 17 have been objected to. Claims 3, 4, 6 and 17 have been amended with this Response. As mentioned below, Applicants respectfully assert that this amendment places the claim set in better condition for appeal, and thus these after-final amendments should be entered by the Examiner.

As a courtesy, this Response is being presented to the Examiner as a draft of the arguments that may be presented by Applicants in a pre-Appeal Brief. Applicants intend to file an Appeal and request a Pre-Appeal Conference if the current rejection of the claims is maintained by the Examiner.

As a preliminary matter, claim 3 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it was asserted that the limitation “shape memory material” has insufficient antecedent basis. This claim has been amended in order to address this issue. Applicants respectfully assert that this amendment places the claim set in better condition for appeal, and thus this after-final amendment should be entered by the Examiner.

Claims 1-3, 5, 8-10, 18, 19, 21, 23 and 24 have been rejected under 35 U.S.C. §102(b) as being anticipated by Moulder, U.S. Patent No. 5,725,004. Applicants respectfully traverse this rejection. In order for a reference to anticipate a claim, each and every element of the claim must be present in the reference. See M.P.E.P. §2131.

Moulder discloses a supported canopy. Figures 1-6A show an umbrella or supported canopy structure 10 having a canopy 12 and a support structure 14. The umbrella 12 has open and collapsed positions. See column 4, lines 41-48. Apparently, the umbrella 12 can have a conduit system 15 that comprises a central conduit 17 extending through a pole 14, the central conduit 17 being in fluid communication with a plurality of stiffenable tubes 18. See column 4, lines 58-67. Hydraulic fluid or other fluid 22 can apparently be present in the conduit system 15, and the fluid 22 can be

pressurized in order to transform the stiffenable tubes 18, moving them from a collapsed position to an open position. See column 5, lines 3-25.

In the Office Action, it was asserted that Moulder discloses an elongate member 14, a frame 15 and an actuation system 18 comprising one or more actuating members which connect the frame 15 to the elongate member 14 and configured to move the frame between an expanded position and a contracted position. Applicants respectfully disagree with this characterization of Moulder, and assert that Moulder does not disclose each and every element of claim 1.

Claim 1 recites, in part, a medical device comprising a blood-impermeable wall, a frame attached to the wall, an elongate member attached to the frame, and an actuating system comprising one or more actuating members, the one or more actuating members connecting the frame to the elongate member. As an initial matter, the claim recites a medical device, and Moulder does not disclose a medical device.

The recitation of a medical device in claim 1 is a recitation of the structure of the claimed device. “The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use ‘can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim.’” See M.P.E.P. §2111.02, citing *Corning Glass Works*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989). In *Corning*, the preamble was considered to add structural limitation to the claimed invention, apparently because it was obvious from the specification that the invention being claimed was an optical waveguide, which was recited in the preamble. The court stated that, “to read the claim in light of the specification indiscriminately to cover all types of optical fibers would be divorced from reality.” *Corning*, 868 F.2d at 1257.

Similarly, in this case, the specification of the invention is dedicated to medical devices. As such, the “medical device” language in the preamble of claim 1 does recite structure, and it must be considered a part of claim 1. Because Moulder does not disclose anything that can be referred to as a medical device, Applicants assert that this reference does not disclose each and every element of claim 1. Applicants respectfully assert that to ignore the language of the preamble and assert that the claim reads on the umbrella or

supported canopy of Moulder would completely ignore the context provided by the specification of the application, and such an interpretation would be, in the words of the *Corning* court, “divorced from reality.” Simply put, this invention is focused on the field of medical devices, and as such claims to a medical device cannot be read to encompass an umbrella or supported canopy as disclosed in Moulder. Thus, Moulder is missing at least this element of claim 1.

In addition, the Office Action appears to point to the conduit system 15 of Moulder as the equivalent of the frame of claim 1 and to the stiffenable tubes 18 as being the equivalent of the actuating system of claim 1. However, as mentioned above, the stiffenable members 18 are actually part of the conduit system 15 of Moulder. Reference numbers 15 and 18 in Moulder are not pointing to separate elements of Moulder. one of the reference numbers 15 is pointing to a portion of the conduit system 15 that is made up of the stiffenable members 18, and reference number 18 is simply pointing to an individual stiffenable member. Thus, to treat reference number 15 and 18 as a frame and actuating system, respectively, is a mischaracterization of this reference. In addition, even if the conduit system 15 could be a frame and the stiffenable members 18 could separately be an actuating system, the stiffenable members 18 do not comprise “one or more actuating members, the one or more actuating members connecting the frame to the elongate member,” as required by claim 1. Simply put, Moulder does not contain all three of the following elements of claim 1: a frame, an elongate member, and an actuating system with actuating members that connect the frame to the elongate member.

Because all elements of claim 1 are not disclosed in Moulder, Applicants respectfully assert that this claim is not anticipated by this reference. Further, because they are dependent on claim 1 and because they contain additional patentably distinct elements, Applicants also assert that claims 2-3, 5, and 8-10 are allowable over this reference.

With respect to claim 3, the Office Actions stated that “it is inherent that the struts formed by the shape memory material are electrically connected to a voltage source.” Applicants respectfully disagree. In order for an element to be inherent, it must necessarily be true that the element is present. See M.P.E.P. §2112. Applicants assert that, because a material can be subjected to an electrical field without being directly

connected to a voltage source, this element if not necessarily present, and thus not inherent, in Moulder. As such, at least this additional element of claim 3 is missing from the disclosure of Moulder, and Applicants assert that claim 3 is allowable over this reference for this additional reason.

Claims 18, 19, 21, 23 and 24 were also rejected under §102(b) as being anticipated by Moulder. Applicants respectfully traverse this rejection. Claim 18 recites, in part, an intravascular pump with a flexible wall defining a pumping chamber and a pumping mechanism. Applicants cannot see how Moulder can possibly be described as an intravascular pump. Moulder does not describe an intravascular device at all, much less an intravascular pump. In the Office Action, it was stated that “a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations.” However, Applicants assert that this is not what is being argued.

Simply put, claim 18 recites an intravascular pump. The recitation of an intravascular pump in the claim is not a recitation of the intended use, but rather is a description of the device itself. As stated above, M.P.E.P. §2111.02, part II and *Corning* explain that whether the preamble is considered a structural limitation must be determined in light of the entire disclosure of the application in order to understand what the inventors invented and what the inventors intended to claim. The specification of the current application is focused on medical devices, and more specifically on coronary assist pumps. Again, Applicants respectfully assert that to ignore the language of the preamble and assert that the claim reads on the umbrella or supported canopy would completely ignore the context provided by the specification of the application, and such an interpretation would be, in the words of the *Corning* court, “divorced from reality.”

Because the phrase “intravascular pump” is a structural limitation of claim 18 and it cannot be said that Moulder discloses an intravascular device at all, much less an intravascular pump, Applicants respectfully assert that each and every element of claim 18 is not present in Moulder. Because they are dependent on allowable claim 18 and because they contain additional patentably distinct elements, Applicants also assert that claims 19, 21, 23 and 24 are allowable over this reference.

Claims 18-20, 24 and 25 were rejected based on 35 U.S.C. §102(b) as being anticipated by Schiff, U.S. Patent No. 4,522,195. Applicant respectfully traverses this rejection. In order for a reference to anticipate a claim, each and every element of the claim must be present in the reference. Apparently, the Examiner is giving no patentable weight to the recitation of the device of claim 18 as an “intravascular pump.” Applicants respectfully disagree with this characterization of claim 18.

As mentioned above, it would be “divorced from reality” not to give the phrase “intravascular pump” in the preamble of claim 18 any structural meaning. As such, this phrase must be considered when comparing the claim to the disclosure of Schiff. In light of this, Applicants respectfully assert that claim 18 recites an intravascular pump. As discussed below, Schiff does not disclose an intravascular pump as recited in claim 18.

Schiff discloses an apparatus for left heart assist. The apparatus can apparently comprise a balloon member and an umbrella member. As stated in column 6, lines 10-15, the function of the prior art balloon of Figure 2 is described as follows: “When the intra-aortic balloon 12 is properly positioned through either femoral artery, the balloon 12 is operated by pulsatile pressure generating means (not shown) for inflating the balloon 12 during diastole and for deflating balloon 12 during systole in order to decrease left ventricular pressure and heart work.” The balloon can apparently create positive or negative pressure at times during the heart pumping cycle in order to make it easier for the heart to pump blood. See, for example, column 6, lines 53-60. Further, the balloon 22 of Figure 3 is said to operate in much the same manner as the balloon of prior art Figure 2. See column 7, lines 5-6.

Schiff appears to introduce an umbrella that can apparently help in eliminating the harmful effects of retrograde flow around the balloon. See, for example, column 6, lines 53-64. The umbrella apparently opens up when blood flows across the umbrella from the closed end toward the open end of the umbrella. Thus, blood flow in this direction is allowed substantially unhindered. The umbrella can then apparently open back up when the blood flow is reversed (when the blood flows in a direction from the open toward the closed end of the umbrella). With the umbrella in an open position, retrograde flow can be diminished or eliminated. This operation of the umbrella is described, for example, at column 7, lines 34-60. Thus, the umbrella of Schiff appears to be a check valve structure

that can selectively allow blood flow through the aortic arch. Simply put, such a structure cannot be called a pump.

In contrast, claim 18 recites an intravascular pump with a flexible wall, the wall defining a pumping chamber. The pump further comprises “a pumping mechanism including a frame attached to the wall.” The flexible wall defines the pumping chamber, and a pumping mechanism is attached to the wall.

The Office Action apparently equates the umbrella of Schiff with the pumping chamber of claim 18, and the stiffeners 28, 29 of Schiff with the frame of claim 18. Applicants respectfully traverse this characterization of Schiff. Schiff does not appear to disclose a structure that could be described as a wall making up a pumping chamber, where a frame is attached to the wall. The umbrella of Schiff that is equated with the pumping chamber of claim 18 simply changes configuration in response to the direction of the blood flow in the aorta. It does not appear to actually be able to pump blood through the aorta. As mentioned above, the umbrella appears to be a check valve, and does not have the ability to pump fluids. The umbrella simply is not a pump. This is not an argument about the intended use. Applicants are simply pointing out that the structure of the umbrella in Schiff is not the structure of a pump, and thus the umbrella cannot be called a pump. Thus, the umbrella of Schiff cannot be the pump of claim 18.

Further, even if the phrase “intravascular pump” in the preamble were ignored, it cannot be ignored that the claim recites a pumping chamber and a pumping mechanism. These elements are necessarily associated with a structure that can be called a pump. Because the umbrella is not a pump, as argued above, the umbrella cannot possibly contain structures that can be called a pumping chamber or a pumping mechanism. Again, this is not, as the Examiner has apparently asserted, an argument about the intended use of the device; rather, this is an argument that the structure recited in this claim is the structure of a pump. Because the umbrella of Schiff is not a pump, it simply cannot contain a pumping chamber or a pumping mechanism.

Because each and every element of claim 18 is not disclosed in Schiff, Applicants respectfully assert that Schiff cannot anticipate claim 18. Because they depend on claim 18 and because they contain additional patentably distinct elements, Applicants also assert that claims 19, 20, 24 and 25 are patentable over Schiff.

Claims 21 and 22 were rejected based on 35 U.S.C. §103(a) as being unpatentable over Schiff in view of Breznock. Applicants respectfully traverse this rejection. In order for a combination of prior art references to render a claim obvious, the prior art references must contain each and every element of the claim.

As mentioned above, Schiff does not contain each and every element of claim 18. In addition, Breznock does not appear to disclose the elements of claim 18 that are missing from Schiff, and thus this combination of references does not contain each and every element of claims 21 and 22. Because this combination of references does not contain each and every element of claims 21 and 22, Schiff in view of Breznock cannot render claims 21 and 22 obvious.

Claim 23 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Schiff. Applicants respectfully traverse this rejection. In order for a combination of references to render a claim obvious, each and every element of the claim must be present in the cited prior art. See M.P.E.P. §2143.03. As mentioned above, Schiff does not disclose each and every element of claim 18, and therefore this reference does not disclose all elements of 23, which depends from claim 18. As such, Applicants assert that claim 23 is allowable over Schiff.

Claim 26 was rejected based on 35 U.S.C. §103(a) as being unpatentable over Schiff in view of Choy et al., U.S. Patent No. 4,771,765 (hereinafter “Choy”). Applicants respectfully traverse this rejection. In order for a combination of prior art references to render a claim obvious, the prior art references must contain each and every element of the claim.

As mentioned above, Schiff does not contain each and every element of claim 18. In addition, Choy does not disclose the elements of claim 18 that are missing from Schiff, and thus this combination of references does not disclose each and every element of claim 26. Because this combination of references does not contain each and every element of claim 26, Schiff in view of Breznock cannot render claim 26 obvious.

Claims 4, 6, 7 and 17 were objected to as being based upon a rejected independent claim, but it was stated that they would be otherwise allowable if re-written in independent form. Claims 4, 6 and 17 have been re-written as requested. Applicants respectfully assert that these after-final amendments should be entered because they place

the claim set in better condition for appeal. Applicants also assert that claim 7 is allowable because it is based on amended claim 6, which the Examiner has indicated is allowable.

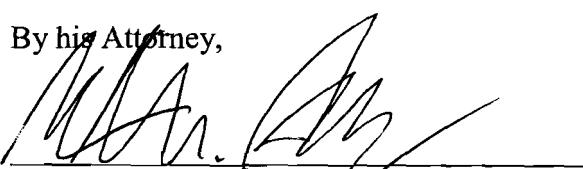
Reexamination and reconsideration are respectfully requested. It is submitted that all pending claims are currently in condition for allowance. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at 612-677-9050.

Respectfully submitted,

BRYAN LEASURE

By his Attorney,

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Glenn M. Seager, Reg. No. 36,926  
CROMPTON, SEAGER & TUFTE, LLC  
1221 Nicollet Avenue, Suite 800  
Minneapolis, Minnesota 55403-2420  
Tel: (612) 677-9050